Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN NGAI, and DAVID LIN

Appeal No. 2002-1092
Application No. 09/597,608

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

Opinion by ADAMS, Administrative Patent Judge.
Opinion dissenting in part by GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 19 and 20. The only other pending claims (claims 1-18) were indicated to be allowable. (Brief, page 1)

Claims 19 and 20 are reproduced below:

19. A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.

20. A kit according to claim 20[1] [sic], comprising premeasured portions of oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.

For convenience claim 1, as it is referred to in claim 19, is reproduced below:

1. A method for normalizing and amplifying an RNA population comprising the steps of:

copying message RNA (mRNA) to form a first single-stranded (ss) cDNA;

converting the first ss-cDNA to a first double-stranded (ds) cDNA;

linearly amplifying the first ds-cDNA to form first amplified RNA (aRNA);

tagging the 3' end of the first aRNA with a known sequence to form 3'-tagged first aRNA;

copying the 3'-tagged first aRNA to form second ss-cDNA; and

normalizing the mRNA or the first aRNA.

The references relied upon by the Examiner are:

Hampson et al. (Hampson)	5,591,575	Jan. 7, 1997
Serafini et al. (Serafini)	6,114,152	Sep. 5, 2000

(Stratagene), Stratagene Catalog, 109 (1995)

GROUNDS OF REJECTION

Claim 19 stands rejected under 35 U.S.C. § 102(b) as anticipated by Stratagene.

[1] We note that claim 20 depends from itself. In an effort to advance prosecution, we recognize that both the Examiner (Answer, page 4) and Appellants (Brief, page 4) treat claim 20 as depending from claim 19. Therefore, for the purposes of this appeal we have interpreted claim 20 as depending from claim 19. Upon further prosecution, we encourage Appellants and the Examiner to work together to correct the dependency of claim 20.

Claim 20 stands rejected under 35 U.S.C. § 103 as being unpatentable over Stratagene in view of Serafini and Hampson.

We affirm the rejection under 35 U.S.C. § 102(b), and reverse the rejection under 35 U.S.C. § 103.

DISCUSSION

THE REJECTION UNDER 35 U.S.C. § 102(b):

"A group or 'kit' of interrelated parts is a 'manufacture' as that term is used in section 101." In re Venezia, 530 F.2d 956, 960, 189 USPQ 149, 153 (CCPA 1976). According to claim 19, the kit comprises instructions describing the method of claim 1 and a premeasured portion of a reagent. In contrast to claim 20, the kit of claim 19 requires that the reagent be selected from a Markush grouping consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides. Note, however, that the method of claim 1 does not expressly require the use of any reagent identified in the Markush grouping set forth in claim 19. Instead, it appears that the use of any reagent selected from the Markush grouping set forth in claim 19 is to be inferred from the steps recited in the method of claim 1. Therefore in its simplest form, the kit according to claim 19 comprises a "premeasured portion" of buffer[2] (a composition) associated with instructions

[2] For convenience we limit our discussion to "buffer" as it is recited in the Markush grouping of claim 19. We could just as well have discussed "nucleotides," as both are taught to be components of the kit taught by Stratagene.

describing the method of claim 1. We reach this conclusion since claim 19 does not (1) characterize the "kit" in any manner, (2) require any specific concentration or amount of reagent, or (3) require the instructions be associated in any manner with the buffer. The only limitation as to the buffer composition is that it is present in a "premeasured portion."

According to the Examiner (Answer, page 3), Stratagene teaches a kit comprising instructions (last sentence under the heading "RAP-PCR PROTOCOL"), and 10X buffer (second line under the heading "CONTENTS RAP-PCR Kit."[3]

According to Appellants (Brief, page 3), Stratagene "does not provide a required element of claim 19 (the required instructions), and hence cannot anticipate the claim. The sole issue in this appeal is whether the Examiner may ignore an express limitation of our claim in order to encompass the cited art."[4] We agree with Appellants (id.), in that an Examiner cannot disregard claim limitations. Instead every limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines. In re Wilder, 429 F.29 447, 450, 166 USPQ 545, 548 (CCPA 1970). In this regard, we note

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[3] We recognize the Examiner's discussion of the Stratagene reference refers to RNase and primers. To clarify the record, Stratagene refers to "RNase block." In contrast to RNase H, "RNase block" inhibits the activity of RNase A, B and C and has no effect on the activity of RNase H. See http://www.stratagene.com/displayProduct.asp?productId=400 (product description of RNase Block Ribonuclease Inhibitor.). In addition, the claimed primers are either an oligo dT T7 biotinylated primer or annealed biotinylated primers. In contrast, the Stratagene reference lists Oligo(dT) primer and β-actin control primers. Stratagene's oligo(dT) primer is distinct from an oligo dT T7 primer, Stratagene's β-actin control primers are not taught to be annealed, and neither are they taught to be biotinylated.

[4] Appellants do not argue that the Stratagene buffer or nucleotides differ from the "premeasured portion" required by claim 19.

that the Examiner expressly found on this record that Stratagene teaches a kit that includes buffer, or nucleotides associated with instructions for the use of the buffer or nucleotides. Answer, page 3.

Appellants take issue (Brief, pages 3-4) with the Examiner's comment at page 3 of the Answer that "no patentable weight is given to the written material in the instructions describing a method." We recognize as Appellants point out (Brief, page 3) that printed instructions may carry patentable weight.

> Differences between an invention and the prior art against it cannot be ignored merely because those differences reside in the content of the printed matter. [The Examiner] cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole.

In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403 (Fed. Cir. 1983). We note, however, "where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight." Id., at 219, 32 USPQ2d at 404.

After careful consideration of the "printed matter" (instructions) in claim 19, it is our opinion that claim 19 does not set forth any functional relationship between the instructions and the buffer that would distinguish the claimed buffer from those taught by Stratagene. In our opinion, the "printed matter" (the instructions) in claim 19 should be treated in the same manner as claim language setting forth an intended use of an old composition, e.g., the language is not ignored, rather, it is not given "patentable weight." In re Pearson, 494 F.2d

1399, 1403, 181 USPQ 641, 644 (CCPA 1974) ("terms [that] merely set forth the intended use for ... an otherwise old composition ... do not differentiate the claimed composition from those known in the prior art.").

According to the court in Pearson, "[i]t seems quite clear to us that one of the compositions admitted to be old by the appellant would not undergo a metamorphosis to a new composition by labeling its container to show that it is a composition suitable for [another use]." See In re Zierden 411 F.2d 1325, 1329, 162 USPQ 102, 104 (CCPA 1969):

> A mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable. As we said in In re Lemin, 51 CCPA 942, 326 F.2d 437, 140 USPQ 273, 276 (1964),
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> > Appellants are clearly correct in demanding that the subject matter as a whole must be considered under 35 U.S.C. 103. But in applying the statutory test, the differences over the prior art must be more substantial than a statement of the intended use of an old composition. ... It seems to us that the composition ... would be exactly the same whether the user were told to cure pneumonia in animals with it ... or to promote plant growth with it (as here). The directions on the label will not change the composition....

See also, In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("[t]he discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to claims to the known composition").

We recognize Appellants' conclusions (Brief, page 4), "[c]laims [sic] 19 is properly limited to kits [sic] which require particular instructions," and (Reply Brief, page 2) "[i]nstructions (i.e. algorithms) can provide not only a proper claim limitation, they can impart patentability even in the absence of the recitation of

other structure." Appellants, however, fail to explain how the "printed matter" (instructions) set forth in claim 19 is functionally related to the "premeasured portion" of buffer claimed. In our opinion, the instructions do not change the old buffer composition.

We recognize Appellants' reference to the USPTO patent database. According to Appellants (Brief, page 4), "hundreds of patents issued in the past few years that clearly rely on the [sic] a printed matter limitation." It is, however, well settled that whether similar claims have been allowed to others is immaterial. In re Giolito, 530 F.2d 397, 400, 188 USPQ 645, 648 (CCPA 1976).[5]

For the foregoing reasons we affirm the rejection of claim 19 under 35 U.S.C. § 102(b) as anticipated by Stratagene.

We recognize the Dissent's characterization of claim 19 as directed to a kit "which comprises instructions ... together with at least one of the chemical compounds required to carry out the" process described in claim 1[6]. Infra, at page 15. Stated differently, and as we have discussed above (page 3), the kit according to claim 19 in its simplest form comprises a "premeasured portion" of buffer associated with instructions describing the method of claim 1. To the extent that the dissent would find that Stratagene does not include instructions for the use of buffer, as we have discussed above (pages 4-5), the Examiner

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[5] To the extent that the Examiner has attempted to explain the basis for the allowance of the cited patents (Answer, page 7), we note that according to MPEP § 1701, PTO employees are not to discuss questions of validity or invalidity of issued U.S. Patents with persons outside the PTO.
[6] We emphasize that the method of claim 1 does not expressly require the use of any reagent identified in the Markush grouping of claim 19. In addition, for clarity, we note that the phrase "at least one" does not appear in claim 19.

expressly found on this record that Stratagene teaches a kit that includes buffer, associated with instructions. Therefore, the only difference between Stratagene and the claimed invention is the content of the "printed material" describing the method of claim 1.

As characterized by the Dissent (infra, at page 23), "[t]he issue is whether the instructions are functionally related to the other claimed elements; i.e., the other elements of the kit." Since the claim includes as an embodiment a "premeasured portion" of buffer associated with instructions, we believe the issue is whether the buffer would undergo a metamorphosis to a new composition simply by associating it, e.g., by labeling its container, with instructions to show that it is a composition suitable for another use. In our opinion, the law is quite clear on these facts, and would indeed compel a conclusion that an old composition would not undergo such a metamorphosis. See, e.g., Pearson, Spada, and Zierden. Therefore, we cannot agree with the Dissent's conclusion that the Stratagene kit does not anticipate claim 19, because the method of appellants' claim 1 was unknown but for Appellants' disclosure. Infra at page 18.

The Dissent appreciates (infra, at page 19) that statements of intended use often appear in the claim's preamble. The preamble, however, is not the only place where intended use statements can be found, as is the case here where they appear in "printed matter" associated with "premeasured portion" of buffer. See e.g., In re Stencel, 828 F.2d 751, 753, 4 USPQ2d 1071, 1073

(Fed. Cir. 1987) (statements of intended use often appear in the claim's preamble, although not necessarily). In addition, the Dissent finds (infra, at page 19), "that a claim to a product is not further limited by recitation of an intended use." In contrast to the Dissent's position (id.), however, we do not see that reducing an intended use to writing and bundling the "printed matter" with an old composition in the form of a kit, provides any more "patentable weight" than simply stating the intended use in the preamble or body portion of a claim directed to the old composition. In our opinion, to find otherwise is an exaltation of form over substance.

On this record, we interpret the claimed "printed matter" for what it is; a statement of the intended use of a "premeasured portion" of buffer. As set forth in In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997):

> It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985) (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) ("[M]ere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 162 (CCPA 1957)

> ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); In re Benner, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). Accordingly, Schreiber's contention that his structure will be used to dispense popcorn does not have patentable weight if the structure is already known, regardless of whether it has ever been used in any way in connection with popcorn.

We recognize the Dissent's argument (infra, at page 20), "Pearson, Zierden, and Lemin were not faced with the facts we have here: there was no express, structural limitation in the claims that was not shown in the prior art." However, as discussed above, the only difference we have on this record is the content of the "printed matter" (the instructions), which defines the intended use of the "premeasured portion" of buffer claimed. Taking the Dissent's argument to its logical conclusion, an old composition (e.g., an adhesive) could be repatented merely by labeling, or packaging, it with instructions describing the new use of the old composition. This is, however, contrary to the law as we understand it. See, e.g., Spada.

We also appreciate the Dissent's discussion of Gulack and Royka. However, we believe that each case supports our position that "printed matter" must be considered in evaluating the claim as a whole. In this regard, we have evaluated the claim as a whole, and have found the "printed matter" to be a statement of the intended use of the "premeasured portion" of buffer. As discussed above, the Stratagene kit also includes instructions for the use of the buffer included in its kit.

As set forth in Hack, 245 F.2d at 248, 114 USPQ at 163 (footnote omitted) while,

> the discovery or invention of a new use of a known process, machine, manufacture, composition of matter or material may be patentable, it is obvious that such use can be nothing other than a method or process. As a matter of claim drafting, therefore, the discoverer of a new use must protect his discovery by means of process or method claims and not product claims.

A mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable, the same is true of a manufacture (a kit) drawn to the new use of an old or obvious composition. Cf. Hack. Therefore, we are compelled to affirm the rejection of claim 19 under 35 U.S.C. § 102(b) as anticipated by Stratagene.

THE REJECTION UNDER 35 U.S.C. § 103:

In rejecting claims under 35 U.S.C. Section 103, the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). "A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." In re Bell, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting In re Rinehart, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). If the Examiner fails to establish a

prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

According to the Examiner (Answer, page 4), "Stratagene teaches a kit for amplifying an RNA population, which contains reverse transcriptase, nucleotides, RNase, primers, buffer, and instructions (page 161 [sic])." The Examiner finds (id.), "Stratagene does not teach the use of biotinylated primers and streptavidin beads, or [sic] polyadenyl transferase, or DNA pol I." To make up for these deficiencies in Stratagene, the Examiner relies on Serafini for a teaching of polyadenyltransferase and DNA polymerase; and Hampson for a teaching of biotinylated primer and streptavidin beads." Id. Based on this evidence, the Examiner concludes (Answer, bridging paragraph, pages 4-5):

> It would have been obvious to one of ordinary skilll [sic] in the art at the time of the invention to modify the kit of Stratagene by adding biotinylated primers and streptavidin beads, as well as polyadenyl transferase and DNA pol I. This is because biotinylated primers and streptavidin beads would have been very effective in capturing and identifying an amplified nucleic acid. It would also have been obvious to add polyadenyl transferase and DNA pol I because polyadenyl transferase was useful for adding poly(A) sequence, and DNA polymerase was necessary for amplification. All of these items would have been useful in a kit because they would have allowed the practitioner to amplify a sequence, capture, and identify said sequence.

According to claim 20 the kit comprises "premeasured portions of oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides." We note that the Examiner's reference (Answer, page 4) to Stratagene's teaching of RNase is factually incorrect. See

supra, at fn. 3. In this regard, we recognize that while Serafini disclose (column 4, lines 40-43), the use of RNase H as part of their method, Hampson disclose (column 8, lines 45-64), the use of RNase H free reverse transcriptase in their methodology. The examiner fails to address this conflict in the art.

In addition, while the Examiner finds (id.) that Stratagene teaches primers, upon close inspection we find that Stratagene does not teach the claimed primers. According to Appellants' claimed invention the primers are either an oligo dT T7 biotinylated primer or annealed biotinylated primers, in contrast the Stratagene reference teaches an oligo(dT) primer and β-actin control primers. To emphasize this point we note that the RAP-PCR Kit taught by Stratagene refers to RNA arbitrarily primed PCR (RAP-PCR). Stratagene, first sentence under the heading "RAP-PCR PROTOCOL."

Furthermore, the Examiner fails to address the claim limitation that requires "T7 RNA polymerase" as a component of the kit. While, Serafini disclose (column 4, lines 35-50 and Figure 1) the use of an oligo dT T7 primer and T7 RNA polymerase, the Examiner fails to explain where in the prior art a suggestion exists to modify the RNA arbitrarily primed PCR kit of Stratagene to include oligo dT T7 primer and T7 RNA polymerase. We remind the Examiner, as set forth in Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000) the:

> "[S]uggestion to combine may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved." ... However, there still must be evidence that "a skilled artisan, confronted with the same problems as the

> inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." ... "[A] rejection cannot be predicated on the mere identification ... of individual components of claimed limitations. Rather particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed."... [Citations omitted].

At best, one could identify individual components of the claimed invention in the evidence relied upon by the Examiner. What is missing, however, is any suggestion to combine these components in the manner claimed. Therefore, it is our opinion that the Examiner failed to meet his burden[7] of establishing a prima facie case of obviousness. Accordingly we reverse the rejection of claim 20 under 35 U.S.C. § 103 as being unpatentable over Stratagene in view of Serafini and Hampson.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

[7] The initial burden of presenting a prima facie case of obviousness rests on the Examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

GRIMES, Administrative Patent Judge, dissenting in part.

I agree with the majority that the rejection of claim 20 should be reversed. However, I respectfully dissent from the affirmance of the examiner's other rejection. In my view, the examiner and the majority have not shown that the prior art identically disclosed the kit of claim 19.

Claim 19, reproduced in the majority opinion, is directed to a "kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the process of claim 1 and a premeasured portion of a reagent" that can be, e.g., buffers. Claim 1, also reproduced by the majority, recites a six-step process and has been allowed by the examiner (see Paper No. 9, mailed April 20, 2001). Thus, claim 19 is directed to a kit "for normalizing and amplifying an RNA population," which comprises instructions describing the novel and nonobvious, six-step process of claim 1, together with at least one of the chemical compounds required to carry out the described process.

The examiner rejected claim 19 as anticipated by Stratagene, which she characterized as "teach[ing] a kit for amplifying an RNA population, which contains reverse transcriptase, nucleotides, RNase, primers and buffer, and instructions." Examiner's Answer, page 3. The examiner implicitly conceded that the Stratagene instructions do not describe the method of instant claim 1, but concluded that claim 19 was anticipated "[b]ecause no patentable weight is given to the written material in the instructions describing a method." Id.

In my view, the examiner has misconstrued the applicable law. "Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior

art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In addition, while claims should be given their broadest reasonable interpretation during examination, they must not be construed so broadly as to vitiate an express limitation. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed. Cir. 1993) ("[T]o construe the claims in the manner suggested by TI would read an express limitation out of the claims. This we will not do."). See also General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1275, 23 USPQ2d 1839, 1840 (Fed. Cir. 1992) ("[E]ach claim is an entity which must be considered as a whole.") (emphasis in original); In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970) ("[E]very limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines.").

In this case, the examiner has apparently conceded that the Stratagene kit does not comprise "instructions describing the method of claim 1" of the instant application. Nonetheless, the examiner has concluded that claim 19 is anticipated by Stratagene because "no patentable weight is given to the written material in the instructions . . . [and therefore the] instructions of the instant kit are not considered to distinguish the claimed kits over the prior art." Examiner's Answer, page 3.

I cannot square the examiner's position with the case law cited above. Since every limitation of the claim must be considered, and since anticipation requires every limitation of the claim to be shown in the prior art, the examiner's concession that Stratagene does not disclose one of the limitations of the claimed kit compels the conclusion that Stratagene does not anticipate claim 19.* That conclusion is strengthened, in this case, by the examiner's allowance of claim 1: how can a kit comprising instructions describing the concededly novel and nonobvious method of claim 1 be identically disclosed in the prior art?

In that respect, this case is analogous to In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995). In Ochiai, the claims were directed to a method of making a novel and nonobvious product, from a novel and nonobvious starting material, via a standard chemical reaction. See id. at 1567, 37 USPQ2d at 1129. The examiner rejected the claimed method and the Board affirmed, on the basis that

> [t]he process steps, "introducing" A into AB or "reacting" A with B are standard processes used by practitioners in the prior art for reacting similar A moieties with the same B moiety. We are in agreement with the examiner that there is nothing unobvious in the particular process chosen and claimed by the appellants.

Id. at 1569, 37 USPQ2d at 1130 (emphasis in original).

The Federal Circuit reversed, because the PTO had impermissibly ignored limitations of the claimed method in evaluating its patentability over the prior art.

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* The examiner sought to avoid this conclusion by reliance on In re Haller, 161 F.2d 280, 73 USPQ 403 (CCPA 1947). My colleagues in the majority choose not to rely on Haller, and with good reason. Haller predates the 1952 Patent Act and, to my knowledge, has not been cited by any court since the 1952 Act went into effect. Its value as precedent, therefore, is nil.

"The test of obviousness vel non is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'" Id. at 1569, 37 USPQ2d at 1131. The court noted that

> [t]he process invention Ochiai recites in claim 6 specifically requires use of none other than its new, nonobvious acid as one of the starting materials. One having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem recited in claim 6. In other words, it would not have been obvious to those of ordinary skill in the art to choose the particular acid of claim 6 as an acylating agent for the known amine for the simple reason that the particular acid was unknown but for Ochiai's disclosure. . . . As one of our predecessor courts had occasion to observe, in a case involving a highly analogous set of facts, "one cannot choose from the unknown." Mancy, 499 F.2d [1289,] 1293, 182 USPQ [303,] 306 [(CCPA 1974)].

Id.

The discussion in Ochiai is directed to obviousness, rather than anticipation, but it applies here as well. If a claimed invention is not rendered obvious by the prior art, a fortiori it is not anticipated either. To paraphrase the Ochiai court, the particular method of Appellants' claim 1 is not described in the instructions in the Stratagene kit for the simple reason that the particular method was unknown but for Appellants' disclosure; one cannot describe the unknown. Thus, the Stratagene kit does not anticipate claim 19.

The majority affirms the examiner's rejection, based, as I understand it, on two rationales. First, the instructions are not functionally related to the other component(s) of the claimed kit, and therefore are not entitled to "patentable weight." Alternatively, the majority construes the instructions as simply setting out the intended use of the claimed kit; since "terms that merely set forth the

intended use for . . . an otherwise old composition. . . do not differentiate the claimed composition from those known in the art," neither do the recited instructions.

I do not find either of these rationales compelling. The claim limitation requiring "instructions describing the process of claim 1" is not simply an intended use of the claimed kit. "Intended use" refers to claim language – usually in the preamble – that states a purpose or intended mode of using a claimed product, but which does not constitute a structural limitation of the claimed product itself. See, e.g., Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999) ("If . . . the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation."); Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("Where . . . a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.").

It is, of course, a general rule that a claim to a product is not further limited by recitation of an intended use. That rule would apply if, e.g., claim 19 was directed to "a composition for use in the method of claim 1, comprising . . . buffer." But it does not apply where, as here, the limitation at issue is a structural

limitation expressly recited in the body of the claim. The cases relied on by the majority do not hold otherwise.

In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974), In re Zierden 411 F.2d 1325 162 USPQ 102 (CCPA 1969), and In re Lemin, 326 F.2d 437, 140 USPQ 273 (1964), all involved claims to compositions per se. See Pearson, 494 F.2d at 1401, 181 USPQ at 643 ("59. An anti-pop and unsound kernel peanut foliage preparation for reducing pops and unsound kernels in peanut plants comprising . . ."); Zierden, 411 F.2d at 1327, 162 USPQ at 103 ("6. A composition for removing and preventing alluvium deposits in water systems consisting essentially of . . ."); Lemin, 326 F.2d at 438, 140 USPQ at 274 ("22. A composition of matter suitable for promoting growth of plants and for protecting them from damage by parasitic plant pathogens which comprises . . .").

The applicants in Pearson and Zierden admitted that the claimed compositions differed from the prior art only in their intended use. See Pearson, 494 F.2d at 1401, 181 USPQ at 644; Zierden, 411 F.2d at 1327, 162 USPQ at 103. In Lemin as well, the composition of Lemin's claim 22 differed from the prior art only by its intended use. See Lemin, 326 F.2d at 438, 140 USPQ at 276.

The courts in Pearson, Zierden, and Lemin were not faced with the facts we have here: there was no express, structural limitation in the claims that was not shown in the prior art. Although the Pearson and Lemin courts speculated that a differently labeled container would not confer patentability on a known composition, those statements were made in the context of claims to

compositions per se, not claims to a kit comprising a composition and specific, novel and nonobvious, instructions. As the majority concedes, the claimed kit is a manufacture, not a composition. See ante, page 3. The statements from Pearson and Lemin pertaining to labeled containers are at best dicta.

The majority also cites In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990), for the proposition that "[t]he discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition." As with the previously discussed cases, this is unquestionably an accurate statement of law, but it does not apply here: Appellants are not claiming a "previously known composition" on the basis of a "new property or use." Appellants are claiming a kit—a manufacture—comprising the known composition together with instructions describing a novel and nonobvious method.

In Spada, the applicants were claiming a composition that contained specific components and had specific properties. See id. at 708, 15 USPQ2d at 1656. The PTO rejected the claims based on prior art that disclosed a composition containing the same components, even though the prior art did not describe the recited properties. See id. The court affirmed the rejection because the prior art reasonably appeared to show the same composition as in Spada's claims, and Spada had presented no evidence to the contrary. See id. at 708, 15 USPQ2d at 1658.

In this case, neither the examiner nor the majority has pointed to any evidence showing that the kit disclosed in the Stratagene catalog would reasonably appear to contain "instructions describing the process of claim 1," as required by claim 19. Spada does not support affirmance of the examiner's rejection.

The majority also relies on In re Gulack, 703 F.2d 1381, 217 USPQ 401 (Fed. Cir. 1983), for the proposition that printed matter must be "functionally related" to the rest of the claimed invention in order to be "entitled to patentable weight." On closer reading, however, the case does not support affirmance here.

Gulack involved a claim to a band having specific digits imprinted on it at regular intervals; the band could be, e.g., a hatband. See 703 F.2d at 1383, 217 USPQ at 402. The digits printed on the band were related according to a specific algorithm, such that the band could be used "to perform magic tricks or to display various aspects of number theory." Id. The PTO rejected the claims as obvious over a reference disclosing "a hat with an endless band having information printed in areas around both the inside and outside of the band." Id. at 1384 n.5, 217 USPQ at 402 n.5.

The Federal Circuit reversed. In doing so, the court held that

> [d]ifferences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter. Under section 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole.

Id. at 1385, 217 USPQ at 403 (footnotes omitted). On the other hand, the court held that differences residing in printed matter will not necessarily distinguish a claimed invention from the prior art. See id. at 1385, 217 USPQ at 404:

> Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight.

(Footnote omitted.)

Gulack's statement that the printed matter must be "functionally related to the substrate" was, of course, made in a context where the invention was the substrate bearing the printed matter (specifically, a band bearing numbers). Thus, where the claimed invention is not simply a substrate bearing the printed matter, Gulack would require that, in order to carry patentable weight, the printed matter must be functionally related to the other elements of the claimed invention.

The pertinent issue, therefore, is not whether the instructions included in the claimed kit are functionally related to the substrate—the paper—on which they are printed. The issue is whether the instructions are functionally related to the other claimed elements; i.e., the other elements of the kit. I conclude that they are, since they provide the guidance required to allow those of skill in the art to use the kit in the method defined by claim 1. Therefore, the claim limitation requiring "instructions describing the process of claim 1" distinguishes the claimed kit from prior art kits such as those disclosed by Stratagene.

A case on point is In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In Royka, the applicant claimed a "device in the nature of an answer sheet for use in self-instruction and testing." Id. at 981, 180 USPQ at 580. The claimed answer sheet functioned as follows:

> The essential features of the invention are that there are printed on the answer sheet in "response areas" meaningful information in permanent printing and confusing information in printing which can be removed, as by an eraser, both being legible so that a student, seeing a choice of answers to a question, must make a selection. Having made a selection, he then applies an eraser to the selected response area and some of the information will be readily removed. What remains advises him of the correctness or otherwise of his answer.

Id.

The PTO had rejected the claims as anticipated by "an answer sheet in which printed information representing a response is 'temporarily concealed from the observer' . . . 'by utilizing the hiding media to confuse the participant and to render the response and the hiding media indistinguishable.'" Id. at 982, 180 USPQ at 581. Thus, the only difference between the claimed answer sheet and the prior art answer sheet was in the content of the printed matter, specifically, the manner in which the respective answer sheets concealed the correct response to a question.

The CCPA reversed the rejection for anticipation. See id. at 984, 180 USPQ at 582:

> It is elementary that to support an anticipation rejection, all elements of the claim must be found in the reference. We do not find claim 28 anticipated by Bernstein because, as we read the claim, it requires the display of legible meaningful and legible confusing information simultaneously. . . . The element we find

> most clearly missing, contrary to the reasoning of the examiner and the board, is the legible confusing information. . . . In appellants' device the legible confusing information—i.e., the wrong answers—are legible in the sense that they can be read as intelligible words, not merely as a jumble of type serving to obscure the words of the wrong answers.

The Royka court also considered a rejection that had been based on the position that the claimed product was "merely a printed matter variation of the design of the reference." See id. at 985, 180 USPQ at 583. The court held that "[t]his is not a valid basis for rejection. Printed matter may very well constitute structural limitations upon which patentability can be predicated." Id. The court reversed the rejection on the basis that "[t]he limitations of claim 36 are not remotely suggested by [the reference]." Id. at 985, 180 USPQ at 583.

In this case, just as in Royka, the printed matter limitation recited in claim 19 is a structural limitation and is not remotely suggested by the prior art. Appellants' claimed kit is therefore not anticipated by Stratagene.

Finally, at the risk of introducing the real world into this discussion, I fail to see why the law should require rejecting the kit of claim 19 in this case. The examiner has already indicated that the method of claim 1 is allowable, and the majority has reversed the rejection of the kit of claim 20. What real-world harm is the majority avoiding by affirming the rejection of claim 19? Are they worried that Appellants will sue Stratagene and everyone else who is selling a labeled bottle of buffer? Surely not – according to its literal terms, claim 19 is limited to a kit comprising "instructions describing the method of claim 1." Appellants will soon have the legal right to exclude others from practicing the method of claim 1; I do

not see that any purpose is served by denying them the right to exclude others from selling a kit comprising "instructions describing the method of claim 1," together with other components.

I would reverse the rejection for anticipation because the prior art cited by the examiner does not disclose all of the limitations of the claimed kit.

Eric Grimes
Administrative Patent Judge

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